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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECHNOLOGY CENTER R3700

In re Application of:)
Serial Number: 10/067,511) Examiner: Anhtuan T. Nguyen
Filed: February 4, 2002) Group Art Unit: 3763
For: DRUG DELIVERY)
NEEDLE DEVICE)
Inventor: Thomas Frederick Enns)

Attorney Docket No.: 11496/9-1052

December 30, 2003

The Assistant Commissioner of Patents
Washington, D.C. 20231
U.S.A.

DECLARATION UNDER 37 CFR 1.131

Dear Sir:

I, Thomas Frederick Enns whose full post office address is 1304 Saginaw Crescent
Mississauga, Ontario, Canada, L5H 1X5, hereby declare and say as follows:

1. I am the named inventor of the subject matter disclosed and claimed in the
above-identified patent application; namely, serial number 10/067,511 filed February 4, 2002.

2. Prior to December 8, 2000, I conceived the above-identified and claimed
invention. I am aware of U.S. Patent 6,613,015 (Sandstrom et al.) filed October 4, 2001 and
PCT patent application WO 02/45574 (Barrus) claiming priority from December 8, 2000. In
order that these documents not be considered as citable prior art against the claims of the
present invention I can establish a date of invention earlier than the filing date of the
Sandstrom et al. reference and earlier than the earliest claim date of the Barrus reference. As
factual evidence of this, the following facts are entered with supporting documentation.

3. Prior to December 8, 2000, I had invented certain novel and inventive improvements in a drug delivery needle device for which I had prepared a set of design drawings for molding of the drug delivery needle device.

4. Enclosed as Exhibit A is a set of computer aided design drawings for the subject matter of the claims of the present patent application. These drawings were provided for the manufacture of a drug delivery needle device and establish a date of design drawings and reduction to practice prior to December 8, 2000. The date of these drawings has been redacted for the protection of the Applicant's confidential information.

5. Enclosed as exhibit B is an invoice issued from a molding company to the assignee of the present patent application, for the manufacture of the prototype drug delivery needle device shown in the Figures of Exhibit A, the date having been redacted. This invoice further establishes a date of reduction to practice prior to December 8, 2000.

6. Enclosed as Exhibit C is a set of computer aided design drawings for the subject matter of the claims of the present patent application, the date having been redacted. These drawings were provided for the manufacture of the drug delivery needle device and further establish a date of reduction to practice prior to October 4, 2001, the filing date of the Sandstrom et al. patent.

7. Evidence providing conception and reduction to practice of the invention before December 8, 2000 is as follows, having regard to the language of claim 1 which reads:

A needle device for percutaneous drug delivery to a patient, the device comprising:
[Reads on: Exhibits A and C, which both show several views of the percutaneous drug delivery needle device, showing reduction to practice prior to December 8, 2000.]

a substantially L-shaped, hollow needle for drug delivery therethrough,
[Reads on: Exhibits A and C, which both show a substantially L-shaped, hollow needle. The substantially L-shaped hollow needle is best shown in the drawing in the lower left-hand corner of Exhibit A and in the lowermost drawing in Exhibit B.]

the needle device including a base,

[Reads on: Exhibits A and C, which both show a base. The base is best shown in the drawing in the upper left-hand corner of Exhibit A and in the lowermost drawing and upper left-hand drawing in Exhibit C.]

a spacer having first and second ends that are longitudinally spaced apart, said first end being integral with said base,

[Reads on: Exhibits A and C, which both show a spacer as defined. The spacer is best shown in the drawing in the upper left-hand corner of Exhibit A and in the lowermost drawing and upper left-hand drawing in Exhibit C.]

and a pair of opposed flexible handles integral with said second end of said spacer, the flexible handles adapted to be grasped for insertion of said needle device into and removal of said needle device from said patient,

[Reads on: Exhibits A and C, which both show a pair of opposed handles. The handles are best shown in the two upper drawings and the drawing in the lower right-hand corner of Exhibit A and in the two upper drawings of Exhibit C.]

a rigid spine located above the spacer and the handles, the rigid spine including a first portion of said L-shaped needle therein,

[Reads on: Exhibits A and C, which both show a rigid spine as defined. The spine is best shown in the two drawings on the left-hand side of Exhibit A and the drawing in the lower right-hand corner of Exhibit A and in the lowermost drawing and upper left-hand drawing in Exhibit C.]

the handles having distal ends movable into contact with each other when the handles are grasped, the handles engaging said spine when said distal ends are in contact.

[Although the device is not shown in use in the computer aided design drawings of Exhibits A and C, Exhibits A and C clearly show grooves that extend along the width of the handles for flexing of the handles along the grooves during grasping. It was clearly intended that these grooves provide for increased flexibility along a preferred line of each of the handles

- such that the handles engage the spine when the distal ends of the handles are in contact. The grooves for flexing are best shown in the drawing in the upper left-hand side and in ghost outline (showing hidden detail) in the two drawings at the right-hand side of Exhibit A. These grooves for flexing are also best shown in the upper and lower drawings and in the left-hand drawing showing a portion of the device drawn to a larger scale, of Exhibit C.

8. It is therefore respectfully submitted that the present patent application claims an invention which was conceived and reduced to practice prior to December 8, 2000.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

Declared at OAKVILLE, Ontario, Canada, the 24 th day of DECEMBER 2003


Thomas/Frederick Enns


Witness